NRC FORM 699
(11-2017)

U.S. NUCLEAR REGULATORY COMMISSION

CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU	DATE OF CONTACT	TYPE OF CONVERSATION
Stacie L. Godin, M.S.	03/29/2019	☐ E-MAIL ☑ TELEPHONE ☐ INCOMING ☐ OUTGOING
E-MAIL ADDRESS	**TELEPHONE NUMBER**	
sgodin@mhopc.com	(574) 204-7885	
ORGANIZATION	**DOCKET NUMBER(S)**	
Michiana Hematology-Oncology, P.C.	030-37858	
LICENSE NAME AND NUMBER(S)	**MAIL CONTROL NUMBER(S)**	
Michiana Hematology-Oncology, P.C./13-32719-01	610915	

SUBJECT
Request for Additional Information re Renewal

SUMMARY AND ACTION REQUIRED (IF ANY)
On 3/29/19, M. Gryglak and S. Godin discussed the following items: see the attached list of items discussed.

NAME OF PERSON DOCUMENTING CONVERSATION
Magdalena R. Gryglak

SIGNATURE	DATE OF SIGNATURE
Magdalena R. Gryglak	3/29/19

In order to continue our review of your renewal, I need additional information. Please refer to NUREG 1556, Volume 9, Revision 2, "Consolidated Guidance About Materials Licenses," which is accessible at https://www.nrc.gov/docs/ML0734/ML073400289.pdf, and Table C.3.

Please provide the following information:

1. For 10 CFR 35.600 material, please confirm:

a. Ir-192 source activity at the time of medical use; and
b. Name of the HDR unit manufacturer/distributor.

2. RSO Delegation of Authority Letter:

Resubmit the RSO Delegation of Authority Letter. A model letter can be found in Appendix I of NUREG 1556, Volume 9, Revision 2. Please ensure that the RSO and senior management official date and sign the letter on the same page.

3. Facility diagram -10 CFR 35.200 and 35.300 material, Mishawaka, Indiana:

a. Resubmit the diagram defining the direction of north and all areas adjacent to the PET/CT room, hot lab, and uptake room 1089. Also, please correct the city name;

b. Confirm that there is no structure below the location of use;

c. Provide the room dimensions or scale for all rooms where radioactive material is stored;

d. Label areas in the diagram inside the hot lab (material storage, waste storage, material receipt area/work area, L-shield, sinks, fume hoods, etc.);

e. Describe measures to secure the radioactive material (e.g. locked door, locked storage etc.).

4. Shielding evaluation - 10 CFR 35.200 material (PET), Mishawaka, Indiana:

a. Please provide a simple and complete shielding calculation, show your work; explain assumptions; define terms, equations, constants, substitutions and parameters, to demonstrate that radiation levels in all adjacent areas, including above and below the rooms where the material is used (PET CT Scan room, currently not addressed, Uptake rooms 1087, 1089, and 1089A) will not exceed the levels in 10 CFR 35.1301 for members of the public and radiation workers.

Please clearly correlate all points for which dose levels are calculated with points on the diagram so corroboration is possible;

b. Describe the type of shielding material/barriers in each room for all adjacent areas, including above and below (i.e. poured concrete, lead etc.);

c. Provide thicknesses of the shielding material/barriers in each room for all adjacent areas, including above and below;

d. Provide distances from the patient/exposed source to the adjacent areas/rooms which will be occupied in each direction, including above and below.

5. Facility Diagram - HDR treatment room, Mishawaka location:

a. Provide the dimensions or the scale of the room, explain what "Unassigned" part of the room is (is the room is divided by a wall);

b. Describe areas below and above the room;

c. Show the direction of north on the diagram and label all areas adjacent to the HDR room, including areas above and below;

d. Show the HDR room and each area immediately surrounding the HDR room and whether they are restricted (R) or unrestricted areas (U) (see 10 CFR 20.1003 for definitions);

e. Show the elevation/grade clearly described and what space is above and below the HDR room; and whether it is restricted (R) restricted (R) or unrestricted areas (U);

f. Indicate clearly on the diagram where you anticipate the patient/"exposed source" to be located within the room during treatments;

g. Label HDR storage.

6. Other equipment and Facilities - HDR treatment room, Mishawaka location.

a. Describe how you will secure: a) the unit; b) the console; c) the console keys; d) and the treatment room when not in use or unattended in accordance with 10 CFR 35.610(a)(1). Describe who will have access to the unit, the console, the console keys, and the HDR treatment room (use specific terms such as RSO, AMP, RSO, etc.);

b. Describe how you will control access to the HDR treatment room (e.g. describe physical barriers such as locked door, signs, alarms, warning lights, etc.);

c. Confirm that only one radiation producing device will be operating at one time in the HDR room in accordance with 10 CFR 35.610(a)(3);

d. Describe the design and the function of your door interlock system in accordance with 10 CFR 35.615(b);

e. Describe your radiation monitoring equipment in the HDR treatment room in accordance with 10 CFR 35.615(c);

f. Describe your viewing and audio systems to permit continues observation and communication with the patient during treatment in accordance with 10 CFR 615(d);

g. Provide a description of the emergency response equipment available near the treatment room to respond to a source remaining in the unshielded position or lodged within the patient following completion of the treatment in accordance with 10 CFR 35.615 (g).

7. Facility diagram -10 CFR 35.200 and 35.300 material, Westville location:

a. Label areas inside the hot lab (material storage, waste storage, material receipt area/work area, L-shield, sinks, fume hoods, etc.);

b. Describe measures to secure the radioactive material;

c. Confirm that there is no occupied spaces above and below (ground).

8. Shielding evaluation - 10 CFR 35.200 material (PET), Westville, Indiana:

a. Please provide a simple and complete shielding calculation, show your work; explain assumptions; define terms, equations, constants, substitutions and parameters, to demonstrate that radiation levels in all adjacent areas, including above and below the PET CT Scan room will not exceed the levels in 10 CFR 35.1301 for members of the public and radiation workers.

Please clearly correlate all points for which dose levels are calculated with points on the diagram so corroboration is possible;

b. Describe the type of shielding material/barriers in the PET CT Scan room for all adjacent areas, including above and below (i.e. poured concrete, lead etc.);

c. Provide thicknesses of the shielding material/barriers in PET CT Scan room for all adjacent areas, including above and below;

d. Provide distances from the patient/exposed source in the PET CT Scan room to the adjacent areas/rooms which will be occupied in each direction, including above and below.

9. Facility Diagram - HDR treatment room, Westville location:

a. Resubmit the diagram showing the direction of north and label all areas adjacent to the HDR room including the "exterior";

b. Confirm that there is no occupied spaces above and below (ground);

c. Show the HDR room and areas immediately surrounding the HDR room and whether they are restricted (R) or unrestricted areas (U) (see 10 CFR 20.1003 for definitions);

d. Show the elevation/grade clearly described and what space is above and below the HDR room; and whether it is restricted (R) restricted (R) or unrestricted areas (U);

e. Indicate clearly on the diagram where you anticipate the patient/"exposed source" to be located within the room during treatments;

f. Label HDR storage.

10. Shielding Evaluation - HDR treatment room, Westville location:

a. Explain the assumption for the Ir-192 source activity at the location in your shielding evaluation;

b. Resubmit your shielding evaluation for the HDR room if a higher activity of Ir- 192 is desired to be used at the time of medical use.

11. Other equipment and Facilities - HDR treatment room, Westville location.

a. Describe how you will secure: a) the unit; b) the console; c) the console keys; d) and the treatment room when not in use or unattended in accordance with 10 CFR 35.610(a)(1). Describe who will have access to the unit, the console, the console keys, and the HDR treatment room (use specific terms such as RSO, AMP, RSO, etc.);

b Describe how you will control access to the HDR treatment room (e.g. describe physical barriers such as locked door, signs, alarms, warning lights, etc.);

c. Confirm that only one radiation producing device will be operating at one time in the HDR room in accordance with 10 CFR 35.610(a)(3);

d. Describe the design and the function of your door interlock system in accordance with 10 CFR 35.615(b);

e. Describe your radiation monitoring equipment in the HDR treatment room in accordance with 10 CFR 35.615(c);

f. Describe your viewing and audio systems to permit continues observation and communication with the patient during treatment in accordance with 10 CFR 615(d);

g. Provide a description of the emergency response equipment available near the treatment room to respond to a source remaining in the unshielded position or lodged within the patient following completion of the treatment in accordance with 10 CFR 35.615 (g).

12. Spot check procedures in accordance with 10 CFR 35.643:

a. Provide your procedures describing when (daily before first use and after each source exchange) and what spot checks will be performed in accordance with requirements in 10 CFR 35.643;

b. Provide your procedures describing how the spot checks will be performed in accordance with requirements in 10 CFR 35.643. Please note that in addition to listing the spot checks, your procedures need to briefly describe how each spot check will be performed. For example, to

check whether the HDR room audio system works, you will turn the system on and have another authorized person enter the HDR room and you will communicate with the individual to ensure you can hear each other:

- Electrical interlocks at the door to the HDR room.
- Source exposure indicator lights on HDR unit, on the control console, and the facility
- Viewing system
- Audio system
- Emergency equipment present
- Radiation monitors used to indicate the source position
- Timer accuracy
- Clock (date and time) in the unit's computer
- Decayed source activity in the unit's;

c. Confirm that "if the results of the checks required in 10 CR 35.343(d) indicate the malfunction of any system, you will lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system."

13. Safety Procedures and Instructions in accordance with 10 CFR 35.610:

a. Define what emergency situation you might encounter (for example patient sickness/loss of power/any HDR system failure etc.);

b. Describe how you will permit only individuals approved by the AU, RSO, or AMP to be present in the treatment room during treatment with the sources in accordance with 10 CFR 35.610(a)(2);

c. Name individuals responsible for implementing corrective actions after an abnormal situation in accordance with 10 CFR 35.610(4)(i);

d. Describe the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure in accordance with 10 CFR (a)(4)(ii);

e. Name and provide the telephone numbers of the AUs, the AMP, and the RSO to be contacted if the unit or console operates abnormally in accordance with 10 CFR 35.610(4)(iii);

f. Confirm that the operating instructions, the emergency procedures and the contact information for the AUs, AMP and RSO will be physically located at the unit console in accordance with 10 CFR 35.61099(b) and (c);

g. Confirm that you will provide instruction, initially and at least annually to all individuals who operate the unit in the emergency procedures, and the operating procedures, in accordance with 10 CFR 35.610(d);

h. Confirm that operators, AMPs, and AUs will participate in drills of the emergency procedures, initially and at least annually, in accordance with 10 CFR 35.610(e).

14. Radiation Monitoring Instruments:

Please resubmit your commitment for Radiation Monitoring Instruments, "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."

15. Occupational Dose:

Please resubmit your commitment for Occupational Dose as described in NUREG 1556, Volume 9, Revision 2, Section 8.23 and Table C.3. Specifically please reference the current revision to the NRC guidance, NUREG 1556, Volume 9, **Revision 2.**

16. Maintenance and waste disposal for HDR units:

Confirm that the manufacturer will perform source exchange and dispose of the Ir-192 sources. Also, the manufacturer will perform maintenance and repairs of the HDR unit.

Gryglak, Magdalena

From: Gryglak, Magdalena
Sent: Wednesday, March 27, 2019 8:52 AM
To: sgodin@mhopc.com
Subject: Additional Information requested, NRC License no. 13-32719-01, Michiana Hematology -Oncology, P.C.
Attachments: Request for Additional Information.docx

Good morning Ms. Godin,

I have reviewed your request dated 12/21/18 to renew your NRC License no. 13-32719-01. In order to proceed with the renewal request, I will need additional information.

I have attached a document listing the additional information needed.

I would like to discuss the content of the document before you provide your response. Please let me know you availability this week (if possible).

Please provide you response in a signed and dated letter by April 27, 2019. You may submit your response as a pdf document and send it directly to me.

Please acknowledge receipt of this email.

Thank you

Magdalena R. Gryglak
U.S. NRC Region III
630-829-9875